

## REMARKS

### **I. Status of the Claims**

At the time of the Action, Claims 45-49 were pending. Claims 45- 49 stand rejected under 35 USC §102(b) as being anticipated. Claims 45, 47, and 49 have been amended and new Claims 50-56 are proffered above. Applicants submit that the present application is now in condition for allowance.

### **II. The Section 102(b) Rejections**

The Action rejects Claims 45-49 under 35 USC §102(b) as being anticipated by Langton et al., Haque et al., and Kobayashi et al. Applicants will address each reference in the order provided in the Action.

i) The Action rejects Claims 45-49 under 35 USC §102(b) as being anticipated by Langton et al. The Action at page 2 states:

Langton et al. disclose fine-stranded gels of both  $\beta$ -lactoglobulin and whey proteins produced at varying pH values.  $\beta$ -lactoglobulin and whey protein concentrate were dissolved in water, and hydrochloric acid was utilized to bring the pH to 4.0 or 3.5. The preparations were then heated at either 85 °C for 30 minutes, or 90 °C for 60 minutes to form the gel. The results demonstrate that both the  $\beta$ -lactoglobulin and whey protein concentrate preparations formed weak, brittle, fine-stranded gels at pH of 4.0 or less when treated with acid and heated. Reference is also made to previous work in the art, where brittle, fine stranded whey protein gels are formed at pH 2.5 upon heating, with subsequent analysis of protein band "possibly corresponding to an acid hydrolysis product of  $\beta$ -lactoglobulin." Note that, although not specifically labeled as such by the reference, this is an FS-II gel, which by definition is a weak fine-stranded gel formed below the isoelectric point of the preparation, as was the case in the reference (Action p. 2, citations omitted).

Applicants submit that the current amendment to Claim 45 obviates the rejection and respectfully request that the rejection be withdrawn. Applicants agree that Langton et al. discloses fine-stranded gels of whey proteins produced in acidic conditions. However, the study of Langton et al. was pure, basic research; the gels were formed in order to study the effect of pH on gel network structure. Whey protein gels are employed in many capacities, including in drug delivery, emulsification, time-release agents, and the like. **Langton et al. does not disclose or suggest using the protein gel produced therein in a composition to enhance the retention of water in the composition.** Applicants have clarified Claim 45 by including the step of introducing the whey protein gel into a composition in order to enhance the retention of water in said composition. Therefore, Applicants

respectfully submit that Langton et al. does not anticipate the methods of the present invention. Applicants further submit that, in view of the failure of Langton et al. to in any manner suggest adding the gel to another composition at all, much less to a composition for the purpose of enhancing water retention, Langton et al. also fails to render the claimed subject matter obvious under Section 103(a).

ii) The Action rejects claims 45-49 under 35 USC §102(b) as being anticipated by Haque et al. The Action at page 2 states:

Haque et al. disclose the production of gels from  $\beta$ -lactoglobulin purified from cheddar whey. Preparations at a pH of 3.5, 7.0 and 9.0 were gradually heated until reaching 90 °C, resulting in "the formation of gels within the cuvette." Note that, although not specifically labeled as such by the reference, this is an FS-II gel, which by definition is a weak fine-stranded gel formed below the isoelectric point of the preparation, as was the case in the reference (Action, p. 2, citations omitted).

Applicants submit that the current amendment to Claim 45 obviates the rejection and respectfully request that the rejection be withdrawn. The protein gels of Haque et al. were formed in order to study the effect of pH and temperature on  $\beta$ -lactoglobulin aggregation. Like the work described in Langton et al., the experiments of Hague et al. are pure research on  $\beta$ -lactoglobulin behavior. **Haque et al. does not disclose or suggest using the protein gel produced therein in a composition to enhance the retention of water in the composition.** Thus, for the same reasons Langton et al. fail to anticipate or render obvious the subject matter of Claim 45, Applicants respectfully submit that Haque et al. does not anticipate or render obvious the recited subject matter.

iii) The Action rejects Claims 45-49 under 35 USC §102(b) as being anticipated by Kobayashi et al. The Action at page 3 states:

Kobayashi et al. disclose bone-enhancing factors made from whey protein preparations. **Reference is made to examples 10 and 11,** where a whey protein concentrate solution is adjusted to a pH of 3.0 or 3.5. The formed precipitate is isolated by centrifugation, and heated at 80 °C for 10 minutes. The product is subsequently lyophilized to form a powder. While the reference does not specifically characterize the product as a gel, it utilizes the same starting materials and protocol steps as the instantly-claimed invention. Thus one of ordinary skill in the art would expect the resultant product to be the same as that produced by the instant invention, namely a fine-stranded gel, absent any clear and

convincing evidence and/or arguments to the contrary. Note also that, although not specifically labeled as such by the reference, this would be an FS-II gel, which by definition is a weak fine-stranded gel formed below the isoelectric point of preparation, as was the case of the reference (Action, p. 3, citations omitted, emphasis added).

Applicants submit that the current amendment to Claim 45 obviates the rejection and respectfully request that the objection be withdrawn. In Kobayashi et al., Examples 10 and 11 describe a method of forming a protein gel by dissolving a protein concentrate in a **3.0M sodium chloride** salt solution. In contrast, the methods of the present invention are largely or completely salt-free, wherein the protein preparation has a salt concentration of between 0 and 100 mM. Further, **Kobayashi et al. does not disclose using a protein gel to enhance water retention.** Therefore, Applicants respectfully submit that Kobayashi et al. does not anticipate or render obvious the methods of the present invention.

### **III. New Claims**

Applicants proffer new Claims 50-56 for entry and examination. Claim 50 depends from Claim 45 and is patentable, at a minimum, for the same reasons set forth above for Claim 45. Claims 51-56 include, *inter alia*, recitations of (a) a protein preparation with a salt concentration between 0 and 100 mM and (b) the step of introducing the protein gel into a composition in order to enhance the retention of water in said composition. Therefore, for the reasons discussed above regarding Claims 45-49, Applicants submit that new Claims 51-56 are also novel and non-obvious.



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Filed 26 March 2003  
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**IV. Conclusion**

Inasmuch as all of the outstanding issues raised in the Action have been addressed, Applicants respectfully submit that the application is in condition for allowance, and request that it be passed to allowance and issue.

Respectfully submitted,

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